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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO.       |
|--|-------------|----------------------|-------------------------------|------------------------|
| 10/048,063   | 01/28/2002  | Norihito Shimono     | 2002-0055A                    | 8747                   |
| 513 7590 07/12/2007<br>WENDEROTH, LIND & PONACK, L.L.P.<br>2033 K STREET N. W.<br>SUITE 800<br>WASHINGTON, DC 20006-1021 |             |                      | EXAMINER<br>YOUNG, MICAH PAUL |                        |
|  |             |                      | ART UNIT<br>1618              | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>07/12/2007       | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/048,063 | <b>Applicant(s)</b><br>SHIMONO ET AL. |  |
|                              | <b>Examiner</b><br>Micah-Paul Young  | <b>Art Unit</b><br>1618               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 April 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29,30,33,34,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29,30,33,34,37 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/17/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

**Acknowledgment of Papers Received:** Amendment/Response dated 4/19/07

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 29,30,33,34,37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner et al (USPN 5,840,332 hereafter '332). The claims are drawn to a process of making a solid product comprising a core, first layer comprising a water-insoluble polymer having chitosan dispersed therein, and an enteric coating, wherein the process comprising coating the core and evaporating the ethanol or water by drying.

2. The '332 patent discloses a solid formulation comprising a core and successive coatings (abstract). The coating composition comprises a water-insoluble carrier with a particulate dispersed therein (col. 9, lin. 38-65). The particulate matter is chitosan, and the water-insoluble include well known such as various Eudragit polymers along with ethylcellulose (*Ibid.*). The form further comprises an enteric coating (claim 4). The enteric coating comprises well-known enteric polymers including those based on methacrylic acid and methyl methacrylate copolymer (claim 17). The dosage form comes as a tablet, or pill, or capsule (abstract), and is designed for colonic delivery (col. 6, lin. 57-65). The reference teaches method of producing the coatings

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including dispersing the solid particulates in the water-insoluble polymer and coating a core pellet (examples). Ethanol is used as a solvent for the coating layer and is driven off by drying (examples).

3. The reference differs from the claims in its exemplified particulate matter and the ratio at which the particles are present in the coating layer. The claims recite a range from 1:4-4:1, where the claims exemplify a ratio from 1:1-3:7. However the 3:7 ratio is encompassed within the wider range of the claimed ratio. Further it remains the position that such modulations in ratio are merely an optimization of ranges. The process of the '332 patent provides sustained release (Figures) of a coated solid dosage form. Also the resulting products are within the same field of endeavor and solve the same problem. It remains the position of the Examiner that the general condition of the claims have been met by the '332 patent.

4. With these things in mind it would be well within the level of skill in the art to follow the teachings and suggestions of '332 in order to produce a solid colonic dosage form. The artisan of ordinary skill would have been motivated to follow these teachings and disclosures with an expected result of a solid formulation useful for colic sustained delivery of active agents.

#### ***Response to Amendment***

5. The Declaration under 37 CFR 1.132 filed 4/19/07 is insufficient to overcome the rejection of claims 29,30,33,34,37 and 38 based upon USC 103 (a) as set forth in the last Office action because: Again the Declaration tests a very specific formulation while the formulation of the instant claims remains broad. Factors such as coating thickness, and particle size are all tested and compared with the prior art, however none of these factors, which would distinguish

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over the prior art, are claimed. Applicant has not compared the exact examples of the prior art to those of the current claimed invention. The tested examples have thickness much lower than that of the prior art, while the particle size is ignored. For these reasons the declaration is not commensurate in scope with the claims and does not overcome the rejection.

***Response to Arguments***

6. Applicant's arguments filed 4/19/07 have been fully considered but they are not persuasive. Applicant argues that:

a. Due to the declaration the Lerner reference no longer obviates the claims.

7. Regarding this argument it is the position of the Examiner that the '332 patent continues to obviate the instant claims in spite of the allegations of the Declaration filed on 4/19/07. As discussed before the declaration is not commensurate in scope with the instant claims, in that the claims only require a ratio of from 1:4-4:1 while the declaration tests discreet points along this range at the end points. It has been the position of the Examiner that the 3:7 and 7:3 ratios of the prior art would fall within the range of ratios recited by the claims. The prior art recites the same polymers (Eudragit RS and ethylcellulose), and the same particulate matter (chitosan) though calcium pectinate is exemplified. It has never been the assertion of the Examiner that calcium pectinate would replace the chitosan, but rather that the selection of a particular particle would be within the level of skill in the art. It is the position of the Examiner that choosing the chitosan as described by the prior art would be within the realm of routine experimentation. It is the position of the Examiner that through routine experimentation an artisan of ordinary skill would be motivated to apply the chitosan recited in the Lerner reference into the coating in order adjust the release of the active agent.

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8. The instant claims recite a preparation comprising a coating comprising chitosan and a water-insoluble polymer in a particular ratio. The Lerner reference discloses a preparation comprising a coating comprising chitosan, and water insoluble polymers in a particular ratio. The ratio proportionally falls within the scope of the claims along with the choice of chitosan. For these reasons the claims remain obviated.

### *Conclusion*

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

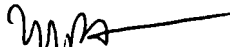
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young  
Examiner  
Art Unit 1618

  
MP Young

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER